K111407

Page 1 of (2)

JAN 18 2012

510(k) SUMMARY
Advanced Surgical Concepts' (ASC)
TriPort 15 Laparoscopic Access Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
USA
Contact Person: Jonathan Kahan
Telephone: +1 202 637 5794
Date Prepared: January 17, 2012

Name of Device and Name/Address of Sponsor

TriPort 15 Laparoscopic Access Device

Advanced Surgical Concepts
Unit 4, Sunnybank Centre
Upper Dargle Road
Bray, Co. Wicklow
Ireland
Contact Person: Ed Hyland
Telephone: +353 (0)1 2864777

Common or Usual Name

Laparoscopic single port access device (Product Code OTJ)

Classification Name

21 C.F.R. §876.1500, Endoscope and accessories
Class II

Predicate Device

ASC TriPort+ Laparoscopic Access Device (K110004)

Intended Use / Indications for Use

The ASC TriPort 15 Laparoscopic Access Device is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.

Technological Characteristics

The ASC TriPort 15 Laparoscopic Access Device is a laparoscopic multi-instrument port which performs the following two functions:

- Retracting a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen at the same time during laparoscopic surgery.

- Ensuring that pneumoperitoneum is maintained in the abdomen during the surgical procedure, whether or not one or more laparoscopic instruments are passing through the device.

The ASC TriPort 15 Laparoscopic Access Device is comprised of the following three components:

- An *introducer component*, which delivers the Distal Ring through a pre-made incision, into the abdominal cavity.

- A *retractor component*, which retracts an abdominal incision to allow the passage of laparoscopic instruments.

- A *valve component* which maintains the pneumoperitoneum established for the surgical procedure.

The minor design changes to the cleared TriPort+ (K110004) device to create the TriPort 15 are as follows:

1. Changing the valve configuration from a four valve (3 x 5mm & 1 x 10mm) to a three valve (2 x 5mm & 1 x 15mm) configuration.

2. The introduction of a new colorant for the 15mm Valve Cap. Note that this portion of the device does not contact the patient.

The changes made to the parent TriPort+ Laparoscopic Access Devices to produce the TriPort 15 are minor and do not represent changes to its intended use, or the operating principles or mechanism of action of the device.

The ASC TriPort 15 Laparoscopic Access Device is sterile and disposable.

Performance Data

Sterilization and shelf life testing, biocompatibility testing, design validation testing, and animal testing of the TriPort 15 was conducted to verify that the changes to the technological characteristics do not affect safety or effectiveness. In all instances, the TriPort 15 functioned as intended.

Substantial Equivalence

The ASC TriPort 15 Laparoscopic Access Device is as safe and effective as the predicate device. The TriPort 15 device has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the TriPort 15 model and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the TriPort 15 is as safe and effective as the predicate device. Thus, the ASC TriPort 15 Laparoscopic Access Device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Surgical Concepts
% Hogan Lovells US LLP
Mr. Jonathan S. Kahan
355 Thirteenth Street, NW
Washington, District of Columbia 20004

JAN 18 2012

Re: K111407
Trade/Device Name: TriPort 15 Laparoscopic Access Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OTJ
Dated: January 17, 2012
Received: January 17, 2012

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. .

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111407

Device Name: TriPort 15 Laparoscopic Access Device

Indications for Use:

The ASC TriPort 15 Laparoscopic Access Device is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111407